

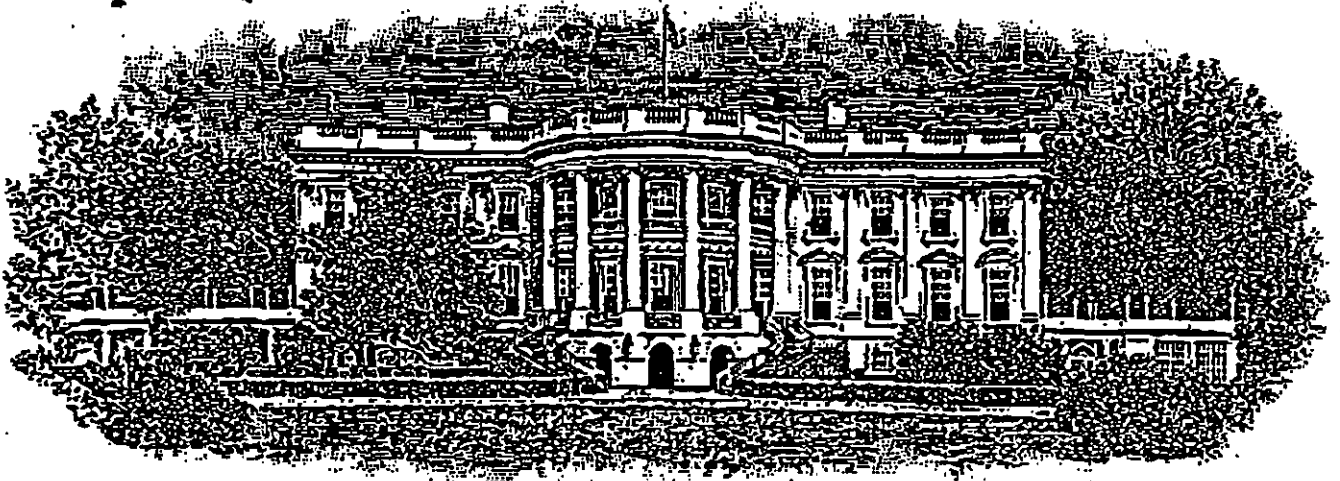
NLWJC - Kagan

DPC - Box 042 - Folder 014

Tobacco-Regulations

Tobacco - regulation

The White House



DOMESTIC POLICY

FACSIMILE TRANSMISSION COVER SHEET

TO: Bruce Reed

FAX NUMBER: 6-2878

TELEPHONE NUMBER: _____

FROM: Elizabeth

TELEPHONE NUMBER: _____

PAGES (INCLUDING COVER): _____

COMMENTS: Linday's drafts w/ Speed writings
Suggestions / edits

STATEMENT BY THE PRESIDENT

This is a landmark day for the nation's public health and for our children. With this ruling, we can regulate tobacco products and protect our children from a lifetime of addiction and the prospect of having their lives cut short by tobacco-related diseases.

[Option One - the Court upholds the advertising restrictions.] We can put Joe Camel and the Marlboro Man out of our children's reach forever.

[Option Two - the Court invalidates the advertising restrictions and no decision has been made about an appeal.] The Department of Justice will review the Judge's decision where he questioned the FDA rule, but the bottom line is historic: the federal government can regulate tobacco products to protect our children's health.

[Option Three - the Court invalidates the advertising restrictions and the decision is made to appeal the ruling.] Senior Attorneys for the Department of Justice, the Department of Health and Human Services, and the Food and Drug Administration have carefully reviewed the District Court's opinion. On the basis of that review, I have directed the Justice Department to proceed with an appeal of the provisions of the rule that the judge did not uphold. But the historic nature of this decision should not be lost: the federal government can regulate tobacco products to protect our children's health.

Our children will live healthier and longer lives because of today's ruling.

STATEMENT BY THE PRESIDENT

The President today expressed his disappointment with the District Court's ruling that the Food and Drug Administration exceeded its jurisdiction in issuing rules governing the access and marketing of tobacco products to teenagers. The President directed the Justice Department to file an appeal immediately. He further directed the Department to seek to expedite the appeal to the maximum extent possible.

The President's action followed a careful review of the District Court's opinion by the senior attorneys for the HHS, FDA, and the Department of Justice. On the basis of that review, ~~the Solicitor General informed the President that an appeal would be appropriate. The President directed that the appeal should go forward immediately.~~ ^{has directed the DOJ}

"This is a fight for the health and lives of our children. Each day, 3,000 young people become regular smokers; 1,000 of these young people will have their lives cut short as a result of smoking. ~~Unless we and the states are allowed to protect our children with effective laws and rules now, five million children alive today will have their lives cut short by the deadly diseases caused by tobacco use.~~ This is a fight we cannot afford to lose. It is a fight we cannot afford to stop waging.

That's why the VP and I are so committed to protecting our young people from tobacco marketing that tempts them

put on Vee

"Our children have the odds stacked against them. The industry spends more than \$5 billion a year promoting and marketing its products. Joe Camel tells our children smoking is cool. The Marlboro Man tells them smoking will make them independent. Virginia Slims and Merit promise them glamour.

to smoke

"Our common sense approach is aimed at limiting the appeal of these products and making it harder for children to buy them. Store clerks have a responsibility to make certain that they are not selling tobacco products to anyone under 18. Asking for a photo ID is just plain common sense. Keeping tobacco billboards away from schools and playgrounds is just plain common sense.

as approp

"We are not walking away from this fight with the tobacco companies. We will protect our children and our children's children. We will not stop until we succeed."

Where our children's health & safety are concerned we cannot, and we will not rest.

Tobacco-
regulation

THE WHITE HOUSE
WASHINGTON

April 17, 1997

MEMORANDUM FOR: Rahm Emanuel
Bruce Lindsey
Ron Klain
Bruce Reed
Elena Kagan
Michael Waldman
Ann Lewis

FROM: Elizabeth Drye 

SUBJECT: Press Materials for Day of and Day After Tobacco Court Decision

Judge Osteen may announce his ruling on FDA's tobacco regulation as soon as Wednesday, April 23. Attached are HHS/FDA press materials (cleared by DOJ) for the day of and the day following the decision:

- 1) Draft press plan;
- 2) Talking points and Q&A for three possible court rulings;
- 3) Draft POTUS statement.

Please let me know if you have comments or questions.

cc: Don Gips
Michelle Crisci
Barbara Woolley
Anne McGuire

draft
4/9/97

April xx, 1997

Note to: WH Press Office, WH Domestic Policy Council
From: HHS/FDA Public Affairs

MEDIA PLAN FOR OPINION DAY AND FOLLOWING

- o White House, FDA press offices field (speaking on the record) initial inquiries using prepared talking points
- o POTUS statement after DOJ, HHS, FDA attorneys review opinion (if appropriate, will announce a decision to appeal)
- o VPOTUS made available for anchor interviews with ABC, CBS, NBC nightly news shows
- o DES made available for one of evening opinion shows (i.e., Lehrer NewsHour, Nightline, Larry King Live)
 - Other HHS/FDA officials (Thurm, Schultz, Zeller) used to fill in behind DES
- o FDA press office will arrange briefings of major editorial pages (NYTimes, WPost, USAToday, LATimes)

Note: Tobacco control activists, state attorneys generals, former FDA Commissioner DAK can also be expected to be interviewed by these media outlets on the day the opinion is issued

Opinion Day +1

- o If a decision to appeal has been made, HHS/FDA can announce filing of notice to appeal
 - HHS/FDA lawyers (Rabb, Schultz, Zeller, Witt) can do on-the-record interviews about legal strength of the rule
 - HHS radio actuality on decision made available nationwide
- o FDA press office will be prepared to answer follow-up questions about impact of opinion on rule (i.e., is FDA continuing to contract with states for enforcement, must retailers continue to check photo IDs for anyone under 27, etc.)
- o FDA press office will arrange briefings of regional editorial writers

4/11/97

FINAL DRAFT

DETERMINED TO BE AN
ADMINISTRATIVE MARKING
INITIALS: Dy DATE: 5/23/10~~CONFIDENTIAL~~ ~~CONFIDENTIAL~~ ~~CONFIDENTIAL~~ ~~CONFIDENTIAL~~

Note to: WH Press Office, Domestic Policy Council

From: HHS, FDA Public Affairs

BACKGROUND

The President announced the FDA rule to protect children from tobacco in August 1996; the rule was immediately challenged by the industry in U.S. District Court in North Carolina. A hearing on the industry's motion for summary judgement was held on February 10, 1997; the judge said he expected to rule on the motion within five to 10 weeks. To be prepared for that ruling, the following scenarios have been sketched out with proposed responses (a statement and back-up questions and answers) to be used by Administration officials. These are draft responses and will be finalized only after a court ruling. The statements and Q-and-A's are to be used by White House and FDA press offices for initial responses after the ruling. A statement by the POTUS will be expected later in the day on the day of the ruling.

SCENARIO ONE

The court rules that FDA has jurisdiction over nicotine-containing tobacco products and rejects the industry's challenge to the final rule.

STATEMENT

The children of the United States won a great victory today. The court upheld the Administration's efforts to kick Joe Camel and the Marlboro Man out of our kids' lives. (Use second sentence only if court upholds advertising restrictions.) Our children will live healthier and longer lives because of today's ruling.

Q: What does this mean in everyday terms?

A: Several of the provisions making it harder for children to buy cigarettes and smokeless tobacco products are already in effect and we are working with states to begin checking for compliance. The provisions to limit the appeal of these products go into effect in August; like we did for the access provisions, we will conduct extensive outreach efforts to educate businesses and the public and will begin working to ensure that these provisions are also enforced.

Q: What about the education campaign that was also announced last August?

A: The FDA is working on contacting the affected companies and will begin consulting with them.

Q: Won't the companies appeal this ruling and/or seek an injunction -- and doesn't that mean delay?

A: You'll have to ask the companies what they intend to do, but our position remains the same as it has been: We are going forward with protecting our children by implementing the rule unless the courts tell us otherwise. We would hope the companies would start working with us to protect our children instead of fighting us every step of the way.

SCENARIO TWO.

The court rules that FDA has jurisdiction, but that portions (or all) of the rule are invalid.

STATEMENT

This is a landmark day for the nation's public health and our children. With this ruling, we can regulate nicotine-containing tobacco products and protect our children from a lifetime of addiction and the prospect of having their lives cut short by tobacco-related diseases. Obviously, we will review the Judge's decision where he questioned the rule, but the bottom line is historic: the federal government can regulate tobacco products to protect our children's health.

Attorneys from the Justice Department, the Department of Health and Human Services and the Food and Drug Administration are already reviewing the opinion, and we expect to announce later today what legal steps we will be taking.

Q: What are you going to do about the provisions of the rule the court struck down?

A: The bottom line is that we are going to protect our children. We're going forward with the provisions the court upheld. We can appeal the ruling or we can redraft the rule with regard to the provisions the court struck down. We will make that decision after we have studied the ruling. (Only HHS and FDA officials should use "we" in speaking about rule-making; White House officials should say "the Agency.")

OR

Q: What are you going to do now that the court has said all the provisions of the rule are invalid?

A: The bottom line is that we are going to protect our children.

We can appeal the ruling or we can redraft the rule. We will make that decision after we have studied the ruling. (Only HHS and FDA officials should use "we" in speaking about rule-making; White House officials should say "the Agency.")

Q: Doesn't this mean more delay?

A: Since the FDA began its inquiry into tobacco in 1994, it has shown repeatedly that it will move quickly to protect our children. The Agency reviewed 700,000-plus comments and published a final rule in a year's time. The Administration will continue to move on other fronts: enforcement of the Synar Amendment, enforcement of existing laws such as the ban on television advertising.

Q: Why not seek a legislative settlement?

A: From the beginning, we have said that if Congress wants to put forth a legislative package as strong as our FDA rule with appropriate oversight and enforcement, we remain prepared to work with Congress.

SCENARIO THREE

The court rules against FDA jurisdiction and rule.

STATEMENT

We are very confident in the Agency's assertion of jurisdiction and the soundness of the rule. We knew from the beginning it would be a long and hard road against the entrenched and powerful interests opposing us, and today's ruling is just the first step. We have to act to protect our children. We are committed to continuing this fight to protect our children and believe we will ultimately succeed. We have to. Each day almost 3,000 young people become regular smokers and nearly 1,000 of them will have their lives shortened from the death and diseases of tobacco use.

Attorneys from the Justice Department, the Department of Health and Human Services and the Food and Drug Administration are already reviewing the opinion, and we expect to announce later today what legal steps we will be taking.

Q: Do you think an appeal will be successful?

A: We believe we have a very strong case and we will ultimately prevail.

Q: Isn't it time to seek legislation?

A: We have been open to a legislative solution that is as strong as the FDA rule with appropriate oversight and enforcement since the President announced the proposal in August 1995. We

are still open to a legislative solution if it accomplishes
our goal of protecting our children.

###

draft
potus statement IF appeal decision is made
4/11/97

The tobacco companies are formidable foes, have no doubt about that. They can pay \$500-an-hour lawyers for years on end. Their lobbyists and influence peddlers can spread millions of dollars around this town election year after election year. But, in the end, all of their money cannot hide the truth. Nicotine is hooking our children. Our children are their new customers. That has to stop.

Secretary Shalala and Solicitor General Delligner have informed me that the Administration will appeal this ruling. Attorneys from the Department of Justice, the Department of Health and Human Services and the Food and Drug Administration immediately reviewed the district court's opinion. They are convinced that we are on solid constitutional and legal ground.

It is also the right thing to do on public health and moral grounds. Let me remind you of why my Administration has taken on the tobacco industry. Each day, 3,000 young people will become regular smokers. Unless we and the states are allowed to protect our children with effective laws and rules, five million children alive today will have their lives cut short by the deadly diseases caused by tobacco use. We are fighting for the health and lives of our children. It is a fight we cannot afford to lose. It is a fight we cannot afford to stop waging.

Our children have the odds stacked against them. The industry spends more than \$5 billion a year promoting and marketing its products. Joe Camel tells our children smoking is cool. The Marlboro Man tells them smoking will make them independent. Virginia Slims and Merit promise them glamour.

Our common sense approach is aimed at limiting the appeal of these products and making it harder for children to buy them. Store clerks have a responsibility to make certain they are not selling tobacco products to anyone under 18. Asking for a photo ID is just plain common sense. Keeping tobacco billboards away from schools and playgrounds is just plain common sense.

We are not walking away from this fight with the tobacco companies. I had hoped they would work with us, but they have chosen a different course. They have made a mistake. We will protect our children and our children's children and the generations to come, and we will not stop until we succeed.

###

Toby Bernstein

4-22 Tobacco

1. Fine Mill - press plan

AN OK - announce intent that day
file the next

2. Response re settlement

- entirely in line to our defense of rule
we're proceeding as if discussions weren't
taking place
- immunity?
sidestep

conventional wisdom:
govt loss → deal
govt win → breakdown

3. Other things down the road.

- Two things not on list:

- excise taxes on tobacco. (HHS supports)
- govt funded anti-tb. PSA campaign -
oppose - undercuts args in lawsuit.
DOJ disagrees - shows how effective advert is.

And two more -

- Med reimb - DOJ and HHS think bad idea.
Why??

- ETC - anything useful?
HHS thinking about?

List - 1st page

- DOJ says, already been as strict as can be,
HHS says, - can try to expand this approach
Can do legislation on this score at least

How did we
hear this?



b) Not very far along

Any other legislative options?

Tobacco
Regulations

April 14, 1997

POTENTIAL TOBACCO ACTIVITIES

Enforcement of broadcast advertising ban. Request the Department of Justice to investigate whether there are other situations similar to that addressed in its consent order with Philip Morris (the Marlboro logo placed in a position at Madison Square Garden so that it appeared frequently during telecasts of New York Knicks games) and encourage the Department to continue its efforts to enforce the ban of broadcast advertising of tobacco products. Enforcement would prevent the broadcast of tobacco brand logos during televised events, particularly sporting events. Sporting events, including auto races, are increasingly popular events with families and are therefore seen by large numbers of young people either in person or on television.

Treatment of adolescent nicotine addiction. Direct DHHS to develop and carry out a federal research plan focusing on the prevention and treatment of adolescent addiction to nicotine. To date, virtually all research that has been conducted on nicotine addiction has focused on adults. It is not known whether currently available prevention strategies and treatments are effective with children and adolescents or whether different approaches are necessary for this group.

State assistance. Direct DHHS to provide technical assistance to states to help develop individual action plans focused on preventing and treating adolescent nicotine addiction. This initiative could build on the results of the federal research in this area described above and could include publication and distribution of guides for states - such as smoking cessation materials aimed at adolescents. It could also involve creating or highlighting public-private partnerships with schools or non-profit groups.

Improved teen surveys. Direct the Office on Smoking and Health, Centers for Disease Control and Prevention, DHHS, to expand its research efforts, especially teen surveys, to include more questions concerning teens' tobacco brand preference and advertising awareness. Further direct the Office of Management and Budget (OMB) to expedite the clearance of the questionnaires used in these surveys. Information on teen preference and awareness is essential to the development of more effective addiction prevention and treatment approaches for adolescents. In the past, OMB has refused to allow certain questions concerning teens' tobacco brand preference and awareness of marketing strategies and slogans to be asked, or if asked, to be publicly reported.

State interventions. Fully fund tobacco intervention programs in all 50 states. This would require a minimum budget increase of \$25 million over the President's 1998 budget. Currently, only 17 states participate in NCI's ASSIST program through which each state receives annual awards that range from \$650,000 a year to \$1.8 million. The remaining 33 states receive annual grants ranging from \$75,000 to \$210,000 through CDC's IMPACT program.

Medicare suits?
FTC?

April 14, 1997

OTHER POTENTIAL TOBACCO ACTIVITIES

Synar regulations. After consulting with the Department of Justice, direct SAMSHA to revisit its Synar regulations and consider making changes that would tighten the standards that States are required to meet in order to qualify for substance abuse block grants. (?)

Smoke-free federal facilities. Issue an Executive Order making all federal facilities smoke-free. GSA could be involved in implementing the Order.

Smoking in the workplace. Encourage the Department of Labor to issue final regulations addressing smoking in the workplace.

Reimbursement for nicotine addiction treatment. Direct DHHS to reimburse for the treatment of nicotine addiction for Federally-funded health care programs and to encourage private sector coverage as well.

Health-focused foreign policy. Direct the U.S. Trade Representative and the State Department to develop trade and foreign policy that emphasizes the Administration's concerns about the health consequences of tobacco use. ✓

Smoke-free transportation facilities. Direct the Department of Transportation to issue regulations making airports (and other transportation facilities under its jurisdiction) smoke-free. Direct the Department to also begin negotiating with foreign governments to obtain an agreement that international flights to the U.S. be made smoke-free.

Conversion of tobacco crop. Announce a program designed to end the tobacco states' dependence on the tobacco economy. Assist and provide incentives to farmers to convert from tobacco crops to other agricultural products, as well as non-agricultural alternatives.]

April 14, 1997

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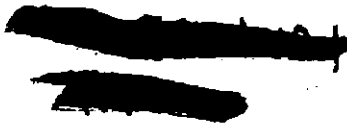
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For 99 budget
need conf.
authorization
for reprogramming



April 14, 1997

OTHER POTENTIAL TOBACCO ACTIVITIES

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Today in Greensboro Judge Osteen denied the tobacco companies' motion for summary judgment that FDA could not legally assert jurisdiction over tobacco products. Judge Osteen expressly held: "tobacco products fit within the FDCA's definitions of 'drug' and 'device.'" The Court further agreed that FDA can regulate cigarettes and smokeless tobacco products under the combination product and restricted device provisions of the Food, Drug, and Cosmetic Act and upheld many of the restrictions imposed by FDA. However, on purely statutory grounds, Judge Osteen found that the restricted device authority does not allow FDA to regulate advertising and promotion of tobacco products.

In reaching his decision, Judge Osteen rejected the tobacco plaintiffs' contention that Congress had preempted the FDA from asserting jurisdiction. Judge Osteen stated, "This court is convinced that neither the text nor the legislative history of the FDCA evidences clear congressional intent to withhold from FDA authority to regulate tobacco products." The Court also refused to bind FDA to statements by prior Commissioners that the agency lacked jurisdiction to regulate tobacco products as customarily marketed or to find that Congress had ratified or acquiesced in those statements.

However, the district court held that FDA lacks authority under Section 360j to regulate promotion and advertising of tobacco products. The court found that the statutory provision giving FDA authority to set "such other conditions" on the sale, distribution, or use of restricted devices does not cover promotion and advertising restrictions.

In sum, FDA's regulations prohibiting the sale of tobacco products to children and adolescents, requiring retailers to check photo identification of purchasers under 27, banning self service and vending machine sales have been upheld, while the limits on advertising and promotion have not. Because of his statute-based ruling on advertising and promotion, Judge Osteen declined to reach the first Amendment challenge to those parts of the regulation.

Tobacco: regulation

tobacco -
~~FDA~~ regulati-

April 25, 1997

Note to: WH Press Office, Domestic Policy Council

From: HHS, FDA Public Affairs

BACKGROUND

The President announced the FDA rule to protect children from tobacco in August 1996; the rule was immediately challenged by the industry in U.S. District Court in North Carolina.

THE DECISION

The court ruled that FDA has jurisdiction and that the rule's access and labeling provisions are still in effect, but that the advertising and promotion portions of the rule are invalid.

STATEMENT

This is a landmark and historic day for the nation's public health and our children. With this ruling, we can regulate nicotine-containing tobacco products and take important steps to protect our children from a lifetime of addiction and the prospect of having their lives cut short by tobacco-related diseases. We have taken a monumental first step down the long, hard road we knew we had to go to protect our children.

Background statement until POTUS statement:

Attorneys from the Justice Department, the Department of Health and Human Services and the Food and Drug Administration have reviewed the opinion and a statement from the President on what the next legal steps the Administration will take will come shortly.

Q: What are you going to do about the provision of the rule the court struck down?

A: The bottom line is that we are going to protect our children. Today, we won a historic victory in court, and we're going forward with the provisions the court upheld.

Q: Doesn't this mean the FDA will have to do something more drastic in terms of access to protect children -- like make these prescription products?

A: We have taken a common sense approach to protect our children by restricting access and we have proposed a common sense approach to limiting appeal. We still believe that is the right way to approach this terrible public health crisis threatening our children.

Q: Doesn't this mean more delay?

A: The access provisions that went into effect in February have been upheld, remain in place and we are working with the states to ensure compliance.

Q: Why not seek a legislative settlement?

A: From the beginning, we have said that if Congress wants to put forth a legislative package as strong as our FDA rule with appropriate oversight and enforcement, we remain prepared to work with Congress.

Q: What does this mean in everyday terms?

A: The provisions that went into effect in February making it harder for children to buy cigarettes and smokeless tobacco products will stay in effect and we are working with states to begin checking for compliance. And it means that FDA has the authority to regulate nicotine-containing tobacco products.

Q: If you appeal, do you think an appeal will be successful?

A: This is an historic decision by the court on the Agency's authority over tobacco products. We believe we have a very strong case and we will ultimately prevail on all parts of the rule to protect our children.

Q: Isn't it time to seek legislation?

A: We have been open to a legislative solution that is as strong as the FDA rule with appropriate oversight and enforcement since the President announced the proposal in August 1995. We are still open to a legislative solution if it accomplishes our goal of protecting our children.

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Questions on Tobacco Settlement Talks

Q. How does the judge's decision affect the Administration's interest in a settlement?

A. I have no idea. Today, we should focus on this ruling. [Go to statement on ruling].

Q. Isn't the Administration deeply involved in settlement talks?

A. Like other parties interested in this issue, we have been monitoring the talks. We have a deep interest in protecting kids and the public health.

Follow-up

Q. But papers have reported that Bruce Lindsey is intimately involved in the settlement talks.

A. My staff are staying informed of the talks, but we are not a party in the talks. My only interest is in protecting kids and the public health.

Q: Would you support a settlement that gives tobacco companies immunity?

A: I'm not in any position to judge any settlement. As I've said, my only interest is in protecting kids and the public's health. We have to do right by them.

Follow-up

Q: Then, what form of immunity would you support?

A: I'm not going to speculate on what the participants in the negotiations might agree to. My Administration proposed the toughest measures ever to protect children from tobacco, and I am going to fight to see that those restrictions take effect. I'm not going to agree to anything with respect to tobacco that jeopardizes the public health. Our focus will stay on protecting kids and the public health.

Follow-up

Q: Anti-tobacco advocates -- including former FDA Commissioner David Kessler -- held a press conference yesterday saying immunity should be off the table altogether. Do you disagree?

A: I have tremendous respect for Dr. Kessler on this issue. Again, I'm not going to support anything that jeopardizes the public health.

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

April 25, 1997

STATEMENT BY THE PRESIDENT

This is a historic and landmark day for the nation's health and children. With this ruling, we can regulate tobacco products and protect our children from a lifetime of addiction and the prospect of having their lives cut short by the diseases that come with that addiction. This is a monumental first step in what we always knew would be a long, tough road, and we are ready to keep pushing on.

This is a fight for the health and lives of our children. Each day, 3,000 children and young people become regular smokers, and 1,000 of them will have their lives cut short as a result of smoking. This is a fight we cannot afford to lose. It is a fight we cannot afford to stop waging. The Vice President and I are committed to protecting our children.

Our common sense approach is aimed at limiting the appeal of these products and making it harder for children to buy them. Retailers have the responsibility to make certain that they are not selling tobacco products to anyone under 18. Asking them for a photo ID is just plain common sense. Keeping tobacco billboards away from schools and playground is just plain common sense.

Senior attorneys from the Department of Justice, the Department of Health and Human Services and the Food and Drug Administration have carefully reviewed the District Court's opinion. On the basis of that review, the Solicitor General has informed me that an appeal would be appropriate for that part of the rule not upheld and I have directed that an appeal be filed.

We will continue to work to protect our children and our children's children. We will not stop until we succeed. Where our children's health and safety are concerned we cannot, and we will not, rest.

Court Decision on FDA Tobacco Rule

Department of Justice Summary

Today in Greensboro Judge Osteen denied the tobacco companies' motion for summary judgment that FDA could not legally assert jurisdiction over tobacco products. Judge Osteen expressly held: "tobacco products fit within the FDCA's definitions of 'drug' and 'device.'" The Court further agreed that FDA can regulate cigarettes and smokeless tobacco products under the combination product and restricted device provisions of the Food, Drug, and Cosmetic Act and upheld many of the restrictions imposed by FDA. However, on purely statutory grounds, Judge Osteen found that the restricted device authority does not allow FDA to regulate advertising and promotion of tobacco products.

In reaching his decision, Judge Osteen rejected the tobacco plaintiffs' contention that Congress had preempted the FDA from asserting jurisdiction. Judge Osteen stated, "This court is convinced that neither the text nor the legislative history of the FDCA evidences clear congressional intent to withhold from FDA authority to regulate tobacco products." The Court also refused to bind FDA to statements by prior Commissioners that the agency lacked jurisdiction to regulate tobacco products as customarily marketed or to find that Congress had ratified or acquiesced in those statements.

However, the district court held that FDA lacks authority under Section 360j to regulate promotion and advertising of tobacco products. The court found that the statutory provision giving FDA authority to set "such other conditions" on the sale, distribution, or use of restricted devices does not cover promotion and advertising restrictions.

In sum, FDA's regulations prohibiting the sale of tobacco products to children and adolescents, requiring retailers to check photo identification of purchasers under 27, banning self service and vending machine sales have been upheld, while the limits on advertising and promotion have not. Because of his statute-based ruling on advertising and promotion, Judge Osteen declined to reach the first Amendment challenge to those parts of the regulation.

Questions on Tobacco Settlement Talks

Q. How does the judge's decision affect the Administration's interest in a settlement?

A. I have no idea. Today, we should focus on this ruling. [Go to statement on ruling].

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A. My staff are staying informed of the talks, but we are not a party in the talks. My only interest is in protecting kids and the public health.

Q: Would you support a settlement that gives tobacco companies immunity?

A: I'm not in any position to judge any settlement. But, I'll say this: everybody agrees that blanket immunity is out of the question. As I've said, my only interest is in protecting kids and the public's health. We have to do right by them.

Follow-up

Q: Then, what form of immunity would you support?

A: I'm not going to speculate on what the participants in the negotiations might agree to. My Administration proposed the toughest measures ever to protect children from tobacco, and I am going to fight to see that those restrictions take effect. I'm not going to agree to anything with respect to tobacco that jeopardizes the public health. Our focus will stay on protecting kids and the public health.

Follow-up

Q: Anti-tobacco advocates -- including former FDA Commissioner David Kessler -- held a press conference yesterday saying immunity should be off the table altogether. Do you disagree?

A: I have tremendous respect for Dr. Kessler on this issue. Again, I'm not going to support anything that jeopardizes the public health.



U.S. Department of Justice

United States Attorney
Middle District of North Carolina

Tobacco-regulation

101 South Edgeworth Street
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TRANSMISSION COVER SHEET

FROM:

W.C. Holton, Jr.
UNITED STATES ATTORNEY'S OFFICE
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Greensboro, North Carolina 27402

Telephone # (910) 333-5351
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TO:

Elizabeth Dreye

FAX NO:

202/456-2878
202/456-7028

RE:

No. Pages 4
(Including cover sheet)

MESSAGE:

DATE:

4-25

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April 25, 1997

Note to: WH Press Office, Domestic Policy Council

From: HHS, FDA Public Affairs

BACKGROUND

The President announced the FDA rule to protect children from tobacco in August 1996; the rule was immediately challenged by the industry in U.S. District Court in North Carolina.

THE DECISION

The court ruled that FDA has jurisdiction and that the rule's access and labeling provisions are still in effect, but that the advertising and promotion portions of the rule are invalid.

STATEMENT

This is a landmark and historic day for the nation's public health and our children. With this ruling, we can regulate nicotine-containing tobacco products and take important steps to protect our children from a lifetime of addiction and the prospect of having their lives cut short by tobacco-related diseases. We have taken a monumental first step down the long, hard road we knew we had to go to protect our children.

Background statement until POTUS statement:

Attorneys from the Justice Department, the Department of Health and Human Services and the Food and Drug Administration have reviewed the opinion and a statement from the President on what the next legal steps the Administration will take will come shortly.

Q: What are you going to do about the provision of the rule the court struck down?

A: The bottom line is that we are going to protect our children. Today, we won a historic victory in court, and we're going forward with the provisions the court upheld. A statement on what next legal steps the Administration will take will come shortly.

Q: Doesn't this mean the FDA will have to do something more drastic in terms of access to protect children -- like make these prescription products?

A: We have taken a common sense approach to protect our children by restricting access and we have proposed a common sense approach to limiting appeal. We still believe that is the right way to approach this terrible public health crisis threatening our children.

Q: Doesn't this mean more delay?

A: The access provisions that went into effect in February have been upheld, remain in place and we are working with the states to ensure compliance.

Q: Why not seek a legislative settlement?

A: From the beginning, we have said that if Congress wants to put forth a legislative package as strong as our FDA rule with appropriate oversight and enforcement, we remain prepared to work with Congress.

Q: What does this mean in everyday terms?

A: The provisions that went into effect in February making it harder for children to buy cigarettes and smokeless tobacco products will stay in effect and we are working with states to begin checking for compliance. And it means that FDA has the authority to regulate nicotine-containing tobacco products.

Q: If you appeal, do you think an appeal will be successful?

A: This is an historic decision by the court on the Agency's authority over tobacco products. We believe we have a very strong case and we will ultimately prevail on all parts of the rule to protect our children.

Q: Isn't it time to seek legislation?

A: We have been open to a legislative solution that is as strong as the FDA rule with appropriate oversight and enforcement since the President announced the proposal in August 1995. We are still open to a legislative solution if it accomplishes our goal of protecting our children.

###

Date: 04/25/97 Time: 12:20

bAHA Hails Decision in Tobacco Industry's Challenge to FDA Rule

To: National Desk, Health Writer

Contact: Trish Moreis of the American Heart Association,
202-822-9380

WASHINGTON, April 25 /U.S. Newswire/ -- Following is a statement by the American Heart Association:

Today the American Heart Association (AHA) reacted with satisfaction to Judge Osteen's decision ruling in favor of the public health interests and against the tobacco industry. This decision was in many respects a complete surprise since this court is in the heart of tobacco country.

The public health community had recognized that there might be a little hope of getting a favorable legal opinion on the FDA's authority over tobacco from this judge in the heart of tobacco country. We are pleased that we were wrong and that the legal facts have finally been acknowledged.

The only issue which Judge Osteen ruled against is FDA authority over advertising. We believe that FDA should and does have the authority (and is within the parameters of the First Amendment) to regulate advertising and we believe that this issue will be overturned.

Judge Osteen's decision, which comes on the heels of the Liggett settlement with 22 attorneys general, marks a truly historical day for the public health of this country.

"Several weeks ago, thousands of documents provided by the Liggett Group Inc., showed what we have always suspected -- that tobacco companies have for decades knowingly marketed their products to children," said Scott Ballin, vice president and legislative counsel, American Heart Association. "These documents also showed that the tobacco companies knew of nicotine's addictive properties and that they distributed their products with the clear intent of keeping their customers addicted. It seems that even a judge in the heart of tobacco country couldn't turn a blind eye to the evidence."

Tobacco is responsible for more than 400,000 deaths each year. Nearly one-third of all smokers will eventually die from their addictions. Smoking among teens, which had been on the decline, has now reached a 17-year high. The evidence of the need for federal authority over tobacco products is stronger than ever. The FDA rule, which is a nationally coordinated program with the authority to restrict tobacco marketing and sales, is the only vehicle to reverse this disturbing trend among teens.

"The battle is far from over," stated Ballin. "The industry will most likely appeal. But we believe that FDA jurisdiction over these deadly products will prevail. Their jurisdiction is supported by the legislative history, FDA's past actions over the regulation of other tobacco and nicotine containing products, and now Judge Osteen's opinion. Recent polls show that 70 percent of the American public believe that the FDA should have authority to regulate the sales and marketing of tobacco products."

Note: Spokespersons are available for print, radio and television interviews on the Greensboro decision.

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/U.S. Newswire 202-347-2770/
APNP-04-25-97 1233EDT

Tobacco regulation

Date: 04/25/97 Time: 11:25

Tobacco companies had no immediate comment on the ruling, but a

Tobacco companies had no immediate comment on the ruling, but a federal official hailed it.

"We are immensely pleased with the court's historic decision today that the FDA has the authority to regulate tobacco products to protect our children's health. This is a great victory for the people of this country," said Assistant Attorney General Frank W. Hunger.

Among the restrictions the FDA had sought are limits on placement of cigarette vending machines. The FDA also had wanted to significantly change tobacco advertising, for example by limiting ads to black and white, with no pictures no Joe Camel, no Marlboro Men on all billboards and in magazines with significant youth readership.

MORE

APNP-04-25-97 1138EDT

Bruce -- two points

1. People here wanted to have the Dept of Justice announce that the SG had made a decision to appeal since (1) the statute and regs require the SG's authorization for taking any appeal and such a decision (like an administrative agency action) should not be made by others and (2) it is important to make clear that any decision to appeal was made after a review of the merits of the District Cts decision. I responded that it was a non-starter to have anyone but the President be taking the active, visible role on this. My best quick shot had making the President the active decisionmaker while preserving the above considerations would go as follows. Share with McCurry if you think appropriate.

The President has directed that an appeal be filed immediately, {and has further directed [the Solicitor General] [the Department of Justice] to seek to expedite the appeal the maximum extent possible.}

The President's action followed a careful review of the District Court's opinion by the senior attorneys for the FDA, HHS and the Department of Justice. On the basis of that review the Solicitor General [authorized an appeal to the Court of Appeals] [informed the President that an appeal would be appropriate.] The President directed that the appeal should go forward [immediately] [promptly].

2. I have thought about the possibility of going directly to the Supreme Court. "Certiorari before judgement" is legally possible but very rare (Steel Seizure; the Iranian Claims Settlement) unless directed by Congress (Communications Decency Act; Line Item Veto).

Advantage: it would lead to the quickest final result

Disadvantage: the court would probably reject the request

fastest schedule would be an October argument and a Jan 98 decision
we could win in the 4th circuit, and most importantly, we could possibly get a 4th circuit decision in time for the August 28 implementation date by successfully arguing for expedition: Gov Br on May 23, Plaintiff's Br on June 17, Govt Reply Brief on June 27, argument on or about July 10 to 15. On that schedule we could possibly get a decision by August 28 lifting the stay and letting the rules go into effect. Or at least we could get one shortly thereafter. -- Walter

Tobacco-regulation

April 24, 1997

NOTE TO: Rahm Emanuel
Bruce Lindsey
Ron Klain
Bruce Reed
Ann Lewis
Michael Waldman
Mike McCurry

FROM: Elizabeth Drye *ED*

SUBJECT: Q&A on Tobacco for Friday's Press Conference

Attached are the Qs&As on the tobacco settlement talks. We will have the Qs&As on the court's 11:00 am decision before noon.

cc: *v* Elena Kagan
Toby Donofield
Julie Mason

Questions on Tobacco Settlement Talks

Q. How does the judge's decision affect the Administration's interest in a settlement?

A. I have no idea. Today, we should focus on this ruling. [Go to statement on ruling].

Q. Isn't the Administration deeply involved in settlement talks?

A. Like other parties interested in this issue, we have been monitoring the talks. We have a deep interest in protecting kids and the public health.

Follow-up

Q. But papers have reported that Bruce Lindsey is intimately involved in the settlement talks.

A. My staff are staying informed of the talks, but we are not a party in the talks. My only interest is in protecting kids and the public health.

Q: Would you support a settlement that gives tobacco companies immunity?

A: I'm not in any position to judge any settlement. But, I'll say this: everybody agrees that blanket immunity is out of the question. As I've said, my only interest is in protecting kids and the public's health. We have to do right by them.

Follow-up

Q: Then, what form of immunity would you support?

A: I'm not going to speculate on what the participants in the negotiations might agree to. My Administration proposed the toughest measures ever to protect children from tobacco, and I am going to fight to see that those restrictions take effect. I'm not going to agree to anything with respect to tobacco that jeopardizes the public health. Our focus will stay on protecting kids and the public health.

Follow-up

Q: Anti-tobacco advocates -- including former FDA Commissioner David Kessler -- held a press conference yesterday saying immunity should be off the table altogether. Do you disagree?

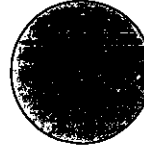
A: I have tremendous respect for Dr. Kessler on this issue. Again, I'm not going to support anything that jeopardizes the public health.

File- Tobacco regulati-

THE WHITE HOUSE
WASHINGTON

March 27, 1997

MEMORANDUM FOR: Rahm Emanuel
Ron Klain
Bruce Lindsey
Bruce Reed



FROM: Elizabeth Drye *ED*

SUBJECT: Draft Response to Possible Court Rulings on FDA Tobacco Regulation

Judge William Osteen may announce his decision on industry's challenge to FDA's tobacco rule as early as Monday, March 31. HHS and DOJ have prepared Administration responses for three possible outcomes (attached). **Please provide any comments on these draft responses to me by COB today (OEOP rm 222; 6-5573).** Elena Kagan and I are setting up a meeting with HHS and DOJ tomorrow afternoon to further refine our response strategy and will notify your office shortly of that meeting.

cc: Elena Kagan
Toby Donenfeld
Michelle Crisci

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INITIALS: Ry DATE: 5/23/98

3/26/97

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FDA, HHS, DOJ reviewed

BACKGROUND

The President announced the FDA rule to protect children from tobacco in August 1996; the rule was immediately challenged by the industry in U.S. District Court in North Carolina. A hearing on the industry's motion for summary judgement was held on February 10, 1997; the judge said he expected to rule on the motion within five to 10 weeks. To be prepared for that ruling, the following scenarios have been sketched out with proposed responses (a statement and back-up questions and answers) to be used by Administration officials. These are draft responses and will be finalized only after a court ruling.

SCENARIO ONE

The court rules that FDA has jurisdiction over nicotine-containing tobacco products and rejects the industry's challenge to the final rule.

STATEMENT

The children of the United States won a great victory today. The court upheld the Administration's efforts to kick Joe Camel and the Marlboro Man out of our kids' lives. (Use second sentence only if court upholds advertising restrictions.) Our children will live healthier and longer lives because of today's ruling.

Q: What does this mean in everyday terms?

A: Several of the provisions making it harder for children to buy cigarettes and smokeless tobacco products are already in effect and we are working with states to begin checking for compliance. The provisions to limit the appeal of these products go into effect in August; like we did for the access provisions, we will conduct extensive outreach efforts to educate businesses and the public and will begin working to ensure that these provisions are also enforced.

Q: What about the education campaign that was also announced last August?

A: The FDA is working on contacting the affected companies and will begin consulting with them.

~~CONFIDENTIAL~~**DRAFT**

Q: Won't the companies appeal this ruling and/or seek an injunction -- and doesn't that mean delay?

A: You'll have to ask the companies what they intend to do, but our position remains the same as it has been: We are going forward with protecting our children by implementing the rule unless the courts tell us otherwise. We would hope the companies would start working with us to protect our children instead of fighting us every step of the way.

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INITIALS: Dy DATE: 5/23/10

SCENARIO TWO

The court rules that FDA has jurisdiction, but that portions (or all) of the rule are invalid.

STATEMENT

This is a landmark day for the nation's public health and our children. With this ruling, we can treat nicotine-containing tobacco products for the public health risk they are, and we can protect our children from a lifetime of addiction and the prospect of having their lives cut short by tobacco-related diseases. Obviously, we will review the Judge's decision where he questioned the rule, but the bottom line is historic: the federal government can regulate tobacco products to protect our children's health.

Q: What are you going to do about the provisions of the rule the court struck down?

A: The bottom line is that we are going to protect our children. We're going forward with the provisions the court upheld. We can appeal the ruling or we can redraft the rule with regard to the provisions the court struck down. We will make that decision after we have had time to study the ruling. (Only HHS and FDA officials should use "we" in speaking about rule-making; White House officials should say "the Agency.")

OR

Q: What are you going to do now that the court has said all the provisions of the rule are invalid?

A: The bottom line is that we are going to protect our children. We can appeal the ruling or we can redraft the rule. We will make that decision after we have had time to study the ruling. (Only HHS and FDA officials should use "we" in speaking about rule-making; White House officials should say "the Agency.")

Q: Doesn't this mean more delay?

A: Since the FDA began its inquiry into tobacco in 1994, it has shown repeatedly that it will move quickly to protect our children. The Agency reviewed 700,000-plus comments and

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INITIALS: RL DATE: 5/23/10

published a final rule in a year's time. The Administration will continue to move on other fronts: enforcement of the Synar Amendment, enforcement of existing laws such as the ban on television advertising.

Q: Why not seek a legislative settlement?

A: From the beginning, we have said that if Congress wants to put forth a legislative package as strong as our FDA rule with appropriate oversight and enforcement, we are prepared to work with Congress. We want action, and to date the only action has come from the President.

SCENARIO THREE

The court rules against FDA jurisdiction and rule.

STATEMENT

We believe we have good grounds to appeal. We knew from the beginning it would be a long and hard road against the entrenched and powerful interests opposing us, and today's ruling is just the first step. We have to act to protect our children. We are committed to continuing this fight to protect our children and believe we will ultimately succeed. We have to. Each day almost 3,000 young people become regular smokers and nearly 1,000 of them will have their lives shortened from the death and diseases of tobacco use.

Q: Do you think an appeal will be successful?

A: We believe we have a very strong case and we will ultimately prevail.

Q: Isn't it time to seek legislation?

A: We have been open to a legislative solution that is as strong as the FDA rule with appropriate oversight and enforcement since the President announced the proposal in August 1995. We are still open to a legislative solution, but we are also going to do all we can to protect our children.

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3/28/97

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FINAL DRAFT

INITIALS: Ry DATE: 5/23/10~~CONFIDENTIAL CONFIDENTIAL CONFIDENTIAL CONFIDENTIAL~~

FDA, HHS, DOJ reviewed

BACKGROUND

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Q: What about the education campaign that was also announced last August?

A: The FDA is working on contacting the affected companies and will begin consulting with them.

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DRAFT

**PRESIDENT WILLIAM J. CLINTON
TOBACCO REGULATIONS ANNOUNCEMENT
THE WHITE HOUSE
FEBRUARY 28, 1997**

*F.L.
Tobacco
Regulations -
Announcement
Events*

Thank you, Anna Santiago for the power of your example and for that warm introduction. I also want to thank the Vice President and Secretary Shalala for their outstanding commitment to this effort. And I want to offer a special word of thanks to David Kessler, the finest FDA Commissioner we have ever had, for your outstanding service to our nation, and especially for your leadership in this effort to protect our young people from the dangers of tobacco. Because of your actions over the last six years, more AIDS and cancer patients are getting better drugs faster. More people are getting better information on their food labels. And every American can go to bed knowing that the food on their tables and the medicines in their cabinets are safe. You have left a great legacy of progress and all Americans should be grateful for your service.

We are all here today to help ensure that Anna Santiago and every young person in this country has a chance to live out their dreams. They can only do that if they choose to live positive and healthy lifestyles, and if we give them the support they need to make that choice. Most of us have an instinctive urge to protect our young people from danger. We teach them to look both ways before crossing the street. We tell them not to touch a hot stove. We make sure they bundle up before going out into the cold. We should wrap that same protective arm around them when it comes to smoking.

More Americans die every year from smoking related diseases than from AIDS, car accidents, murders, suicides and fires combined. Today, it is estimated that 4.5 million of our children and adolescents smoke, and another 1 million use smokeless tobacco. And the problem is getting worse. Smoking rates among eighth graders have risen 50 percent in the last six years. One out of every three young persons who picks up this deadly habit will have their lives shortened from the terrible diseases caused by smoking. We, as parents, as leaders and as citizens have a moral obligation to do what we can to protect those precious young lives.

That is why last August, the FDA took bold action to protect our children from the dangers of tobacco. We set a goal of reducing tobacco use by children and adolescents by 50 percent in seven years. To do that, we initiated the nation's first-ever comprehensive effort to restrict access and limit the appeal of tobacco to children.

Today is the first day that some of these rules take effect. First, we are making the law of the land what already is the law in every state -- no sale of tobacco products to anyone under the age of 18. Second, we are now requiring age verification by photo ID for anyone under the age of 27 before the purchase of tobacco products. From now on, in every store in America, our children will be told "no ID, no sale." By requiring ID checks for anyone under 27, store clerks and managers will no longer have to guess the age of those seeking to buy cigarettes. Studies show that minors succeed in buying cigarettes over-the-counter nearly 70 percent of the time. That simply must stop. With this new requirement to check IDs, we will help keep cigarettes out of reach of our young people while giving

store clerks and managers a tool to make sure they are not violating the law by selling to minors.

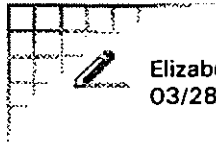
Over the last three weeks, we have conducted a massive nationwide education campaign to let retailers know how they can comply with these new rules. We have even prepared this new guide [hold up brochure] and made it available to 500,000 retailers across the country. **I call on every retailer in every community across this country to join with us in this important effort to protect our children. Parents must continue to be the first line of defense. But it is up to all of us to make these rules work.** Let me be clear -- cigarettes are a legal product for adults. If they want to smoke, they can still do so. But, we must draw the line at our children.

Thank you.

Romer / for Levitt (Utah)
Western Gov. Univ. plan
state-based computer univ.

Think we should do it.

~~Romer~~
May be prob w/ date



Elizabeth Drye
03/28/97 10:18:11 AM

Record Type: Record

To: Elena Kagan/OPD/EOP, Bruce N. Reed/OPD/EOP

cc:

Subject: Food safety and tobacco

Tobacco -- At today's kick butts planning meeting (2:00) I suggest we advocate that the President speak out about recent aggressive tobacco advertising practices. The President could call on companies to act with moral courage and restraint. Companies are not yet using the Internet to advertise directly at US sites, but they are using it in subtle new ways that might recruit youth smokers. Further, companies have recently used bold new advertising tactics that reach youth in other media. For example, RJ Reynolds has moved attractive Joe Camel imagery right onto cigarette packs and is marketing a "collector pack" series. Virginia slims is also currently sponsoring a concert tour and CD for young new women artists as part of its "It's a woman's thing" campaign (ugh). Administration staff and outside groups agree it's a good time for some strong words from POTUS.

Food Safety -- USDA/FDA/CDC are holding a 2 1/2 day meeting M-W next week to work with groups on the President's food safety initiative. They've asked me to speak Monday a.m. for 15 minutes outlining the initiative. We expect about 200-300 people from industry trade associations, science associations, and consumer advocacy groups. As you know, I met with the senior people from most of the key groups in White House meetings in early March. Is it o.k. for me to speak? Do you want to review my remarks? Could be trade press there.

President Clinton Announces First Actions
under FDA's Rule to Protect Children from Tobacco
February 28, 1997 -- THIS DRAFT NOT FOR DISTRIBUTION

Announcement

- o **President Clinton announced that today the Federal government is taking the first steps under the Food and Drug Administration's rule to restrict children's access to tobacco products.** Beginning today, provisions of FDA's rule:
 - o **Prohibit retailers from selling cigarettes and smokeless tobacco products to anyone under age 18** -- this age restriction becomes a Federally enforceable regulation, giving retailers a greater incentive to meet the requirement.
 - o **Require retailers to verify age by photo ID for anyone under the age of 27 purchasing these products.** Most state attorneys general, and even tobacco retailers, have indicated the need for checking IDs of customers significantly older than 18 so that retailers don't sell to mature-looking adolescents.

Background

- o **President Clinton announced the final FDA rule to protect children from tobacco on August 23, 1996.** The rule seeks to reduce children's tobacco use by 50% over seven years by restricting children's access to tobacco and by reducing the appeal of cigarettes and smokeless tobacco products to children. The first two provisions of the rule take effect today.
- o **Youth smoking is on the rise.** Each day about 3000 American children become regular smokers. Of these, 1,000 will die early from tobacco-related illness. In the past six years, the smoking rate among eighth graders has risen 50%. Today the average teenage smoker begins to smoke at 14 ½ years old and becomes a daily smoker before age 18.
- o **Youth have widespread access to tobacco products.** Although selling cigarettes to people under 18 is already against the law in all 50 states, studies show that young people easily obtain tobacco products. Most children and adolescents who smoke purchase their own cigarettes. National data from the 1995 Youth Risk Behavior Survey show that over three-quarters of high school students under age 18 who had purchased cigarettes in the previous month had not been asked by a clerk to show proof of age. Local studies have shown that enforcement of minors' access laws -- especially laws requiring the retailer to check for proof of age -- can significantly reduce the percentage of retailers who sell cigarettes to minors.

Additional Provisions to Restrict Access and Reduce Appeal Take Effect Later this Year

- o On August 28, 1997, additional provisions of FDA's rule become effective. They include: prohibiting billboards within 1,000 feet of schools and playgrounds and restricting other advertising to black-and-white text only except in locations only accessible to adults; permitting black-and-white text only advertising in publications with significant youth readership; prohibiting the sale or giveaways of products like caps or gym bags that carry cigarette or smokeless tobacco product brand names or logos; and prohibiting vending machines and self-service displays except in places where people under 18 are never present.
- o On August 28, 1998, FDA's final rule will prohibit the brand-name sponsorship of sporting or entertainment events. The rule permits sponsorship in the corporate name.

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FDA, HHS, DOJ reviewed

BACKGROUND

The President announced the FDA rule to protect children from tobacco in August 1996; the rule was immediately challenged by the industry in U.S. District Court in North Carolina. A hearing on the industry's motion for summary judgement was held on February 10, 1997; the judge said he expected to rule on the motion within five to 10 weeks. To be prepared for that ruling, the following scenarios have been sketched out with proposed responses (a statement and back-up questions and answers) to be used by Administration officials. These are draft responses and will be finalized only after a court ruling.

SCENARIO ONE

The court rules that FDA has jurisdiction over nicotine-containing tobacco products and rejects the industry's challenge to the final rule.

STATEMENT

The children of the United States won a great victory today. The court upheld the Administration's efforts to kick Joe Camel and the Marlboro Man out of our kids' lives. (Use second sentence only if court upholds advertising restrictions.) Our children will live healthier and longer lives because of today's ruling.

Q: What does this mean in everyday terms?

A: Several of the provisions making it harder for children to buy cigarettes and smokeless tobacco products are already in effect and we are working with states to begin checking for compliance. The provisions to limit the appeal of these products go into effect in August; like we did for the access provisions, we will conduct extensive outreach efforts to educate businesses and the public and will begin working to ensure that these provisions are also enforced.

Q: What about the education campaign that was also announced last August?

A: The FDA is working on contacting the affected companies and will begin consulting with them.

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Q: Won't the companies appeal this ruling and/or seek an injunction -- and doesn't that mean delay?

A: You'll have to ask the companies what they intend to do, but our position remains the same as it has been: We are going forward with protecting our children by implementing the rule unless the courts tell us otherwise. We would hope the companies would start working with us to protect our children instead of fighting us every step of the way.

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SCENARIO TWO

The court rules that FDA has jurisdiction, but that portions (or all) of the rule are invalid.

INITIALS: Ph DATE: 5/23/10

STATEMENT

This is a landmark day for the nation's public health and our children. With this ruling, we can treat nicotine-containing tobacco products for the public health risk they are, and we can protect our children from a lifetime of addiction and the prospect of having their lives cut short by tobacco-related diseases. Obviously, we will review the Judge's decision where he questioned the rule, but the bottom line is historic: the federal government can regulate tobacco products to protect our children's health.

Q: What are you going to do about the provisions of the rule the court struck down?

A: The bottom line is that we are going to protect our children. We're going forward with the provisions the court upheld. We can appeal the ruling or we can redraft the rule with regard to the provisions the court struck down. We will make that decision after we have had time to study the ruling. (Only HHS and FDA officials should use "we" in speaking about rule-making; White House officials should say "the Agency.")

OR

Q: What are you going to do now that the court has said all the provisions of the rule are invalid?

A: The bottom line is that we are going to protect our children. We can appeal the ruling or we can redraft the rule. We will make that decision after we have had time to study the ruling. (Only HHS and FDA officials should use "we" in speaking about rule-making; White House officials should say "the Agency.")

Q: Doesn't this mean more delay?

A: Since the FDA began its inquiry into tobacco in 1994, it has shown repeatedly that it will move quickly to protect our children. The Agency reviewed 700,000-plus comments and

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published a final rule in a year's time. The Administration will continue to move on other fronts: enforcement of the Synar Amendment, enforcement of existing laws such as the ban on television advertising.

Q: Why not seek a legislative settlement?

A: From the beginning, we have said that if Congress wants to put forth a legislative package as strong as our FDA rule with appropriate oversight and enforcement, we are prepared to work with Congress. We want action, and to date the only action has come from the President.

SCENARIO THREE

The court rules against FDA jurisdiction and rule.

STATEMENT

We believe we have good grounds to appeal. We knew from the beginning it would be a long and hard road against the entrenched and powerful interests opposing us, and today's ruling is just the first step. We have to act to protect our children. We are committed to continuing this fight to protect our children and believe we will ultimately succeed. We have to. Each day almost 3,000 young people become regular smokers and nearly 1,000 of them will have their lives shortened from the death and diseases of tobacco use.

Q: Do you think an appeal will be successful?

A: We believe we have a very strong case and we will ultimately prevail.

Q: Isn't it time to seek legislation?

A: We have been open to a legislative solution that is as strong as the FDA rule with appropriate oversight and enforcement since the President announced the proposal in August 1995. We are still open to a legislative solution, but we are also going to do all we can to protect our children.

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March 12, 1997

MEMORANDUM FOR THE PRESIDENT

FROM: Elizabeth Drye, DPC

SUBJECT: Update on Tobacco Issues for North Carolina Trip

Implementation of FDA Rule

As you know, the first two provisions of the FDA's tobacco regulation took effect February 28, prohibiting retailers from selling cigarettes and smokeless tobacco products to persons under age 18 (already state law in all states) and requiring retailers to check photo identification for all individuals under age 27. FDA has conducted an extensive outreach program to inform retailers and communities about these requirements. To enforce the rule, FDA will first send a warning letter to any retailer who sells tobacco products to minors. Retailers who violate the rule a second time will be subject to civil money penalties.

Most other provisions of the FDA rule, including restrictions on advertising, take effect August 28, 1997. The prohibition on sponsoring sporting events applies one year later. You've asked Congress for \$34 million in FY 98 to implement the rule.

Status of Litigation

As you know, manufacturers of cigarettes and smokeless tobacco, the American Advertising Federation, the National Association of Convenience Stores and others have challenged FDA's rule in court. North Carolina filed an amicus brief opposing the FDA rule. The suits have been consolidated, and on February 10, Judge William Osteen of the Federal District Court in Greensboro, North Carolina heard oral arguments. He expects to rule within 5-10 weeks from that date (i.e. between March 17 and April 21).

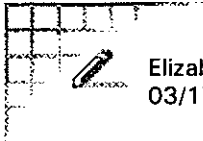
Debate in North Carolina State Legislature on Access Restrictions

The state legislature is considering a bill, proposed by N.C. Attorney General Mike Easley, to strengthen the state law prohibiting sales to minors. The legislation, supported by the tobacco industry and the health community, would remove the word "knowingly" from the state prohibition against knowingly selling cigarettes to people under 18. Like other industry-supported bills, it would strengthen penalties for kids who purchase cigarettes; specifically, it makes using a fake ID a

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misdemeanor. Proponents assert that this law will reduce the need for the access restrictions in FDA's rule, but in debate on the bill some Senators argued that local police won't enforce the state law given competing priorities.

State laws restricting sales to kids have largely failed; studies show minors succeed at buying cigarettes over-the-counter nearly 70% of the time. The FDA requirement to check ID provides a critical, added incentive for retailers to stop selling tobacco products to children.



Elizabeth Drye
03/17/97 11:27:17 AM

Record Type: Record

To: Elena Kagan/OPD/EOP, Bruce N. Reed/OPD/EOP

cc:

Subject: FYI -- Timing of Tobacco Ruling

Judge Osteen stated Friday that he will not issue a decision on FDA's rule before March 24, so we have this week to prepare to respond.